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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/989,342

11/20/2001

Robert C. Simpson

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11/06/2003

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EXAMINER

WILLIAMS, CATHERINE SERKE

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 11/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/989,342

Applicant(s)

SIMPSON, ROBERT C.

Examiner

Catherine S. Williams

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,4. 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I in Paper No. 5 is acknowledged.

Claim Objections

Claims 2 and 12 are objected to because of the following informalities:

A. The limitation of "an inner cavity" has already been positively set forth in claims 1 and 11, respectively. Hence one is confused if this is the already mentioned cavity of claims 1 and 11 or an additional cavity. It is suggested that the recitation and all following recitations be changed to either "the inner cavity" or "a second inner cavity".

B. The phrase "wherein the proximal end piece defines a loading aperture such that the catheter may be loaded or adjusted into the inner cavity through the loading aperture" is duplicate language already introduced in claims 1 and 11. It is suggested that this claim language be deleted in order to avoid confusion.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-4 and 13-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 3763

The term "no larger than a human hand" in claim 3-4 and 13-14 is a relative term which renders the claim indefinite. The term "no larger than a human hand" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. Human hands are not a standard term of measurement and everyone's hand is of a different size. For example, children and adults have hands that are very different in size. One cannot ascertain from the claim or the specification what size would be too large to be within or outside of the scope of the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7 and 10-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuntz (US pat# 3,683,928). Kuntz discloses a catheter applicator. See figures 3-4. The device includes a sidewall (14') with a distal end piece (90), a proximal end piece (12'), a loading aperture (see figure 4), an inner cavity (between 14' and 18') and a dispensing aperture (102). The device is disclosed as being held within a users hand and being made from semi-rigid material (thermoplastic). The sidewall has the shape of a cone, see figure (3-4). The catheter is loaded manually.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kuntz. Kuntz meets the claim limitations as described above but fails to include the dispenser being positioned with the distal end directed toward the user's thumb.

However, at the time of the invention, it would have been obvious to turn the dispenser in any orientation including having the distal end directed toward the user's thumb. The motivation for the alteration would have been in order to enhance the comfort of the device during use to the user or in order to enhance the usability of the device to facilitate the use of the device in hard to reach areas.

Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuntz. Kuntz meets the claim limitations as described above but fails to include the shape of the sidewall as a cylinder or polyhedron.

At the time of the invention, it would have been obvious to change the shape of the sidewall. Further the Federal Circuit has held, where the only difference between the prior art and the claims was a recitation of relative dimension/size/proportion of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art

Art Unit: 3763

device, the claimed device was not patentably distinct from the prior art device. The motivation for changing the shape would have been in order to enhance the usability of the device.


Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuntz. Kuntz meets the claim limitations as described above but fails to include the loading the dispenser mechanically or by an automated process. However, Kuntz does teach that an objective of the device is to keep the catheter aseptic during insertion. Therefore, at the time of the invention, it would have been obvious to load the catheter either mechanically or by an automated process in order to eliminate human contact before use and thereby enhance the sterility of the device prior to use.


Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Pat# 5,611,428 and 6,231,564 disclose analogous inventions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Catherine S. Williams 
November 3, 2003


BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700